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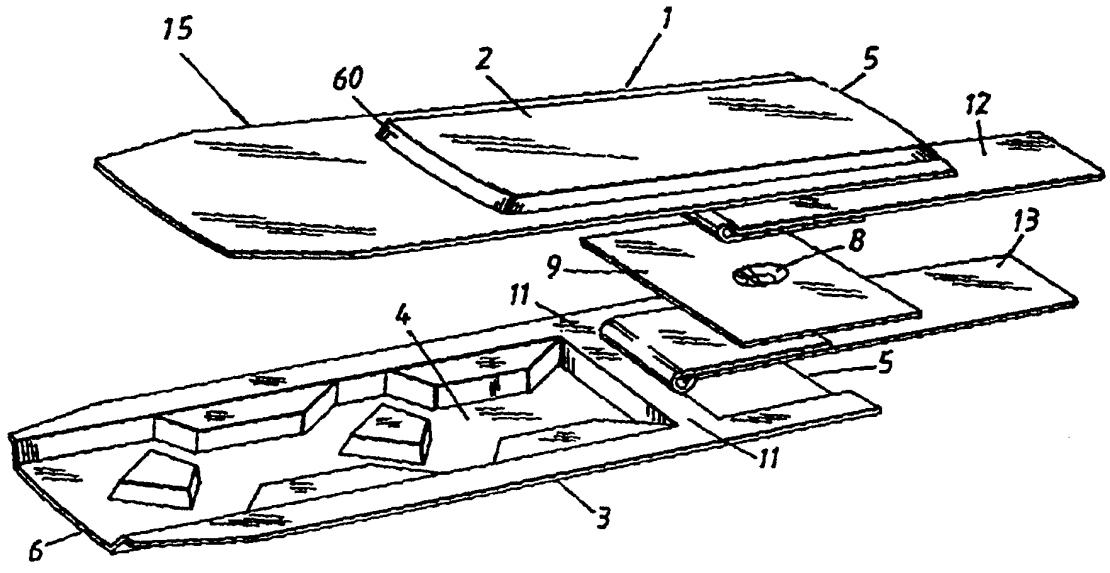

(57) Abstract

Disposable inhaler comprising a tubular housing forming an air flow path being open at both ends, one end forming an air inlet and one end forming an air outlet, said housing comprising a compartment for storing a pharmaceutically active substance to be inhaled, said compartment being placed in the air flow path close to the air inlet, wherein the powder compartment is formed as a cavity or indent in a plate and placed in the housing in the air flow path. According to the invention there is also provided a method of manufacturing the inhaler as well as a use of the inhaler.

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The invention

The present invention relates to a disposable inhaler comprising a tubular housing forming an air flow path being open at both ends, one end forming an air inlet and one end forming an air outlet, said housing comprising a compartment for storing a pharmaceutically active substance to be inhaled, said compartment being placed in the air flow path close to the air inlet.

Inhalers of the above mentioned type are intended to carry a unit dose of a powdered pharmaceutically active substance or a mixture including such substance whereby the particle size of the dose to be inhaled is smaller than 10 μm, preferably smaller than 5 μm.

Background of the invention

Disposable, breath-actuated inhalers are known in the prior art. In most of the known inhalers the powder to be inhaled is loosely provided in the inhalation channel as can be seen in for example in EP-A-0 404 454 and US-A-4 265 236.

In the known above-mentioned devices the powder is provided loosely in a relative large chamber which functions as powder compartment and inhalation channel being provided with air inlet and outlet. The powder in the inhalation devices of the above-mentioned type has a particle size which is generally smaller than 10 μm whereby strong cohesive forces are present between the powder particles. These cohesive forces causes the creation of aggregates of powder which are created during handling and storage of the inhaler . When the powder is freely movable within a chamber as in the above mentioned documents an uncontrolled creation of aggregates will occur. These aggregates could either be to big to be inhaled or too big to enter into the bronchial region of the patient, e.g. larger than

10 µm. With the powder freely movable within a chamber the powder will also stick to the walls due to the adhesive forces between the particles and the walls as well as to electrostatic forces occurring in the device.

These drawbacks are solved in the inhalation devices as described in WO 92/04069 and WO 93/17728. In the constructions according to these applications the powder is provided in a compartment which is provided as an indent or cavity in the lower part of the housing of the inhaler. The powder compartment, the cavity, is provided close to the air inlet, and the air flow path is provided with a constriction adjacent the powder compartment in order to create an acceleration of the air flow to lift the powder dose out of the cavity and mix it with the inhalation air flow during inhalation. In WO 93/17728 a hole is provided in the cavity in order to facilitate the lifting of the dose into the inhalation air flow. In order to break down the aggregates of the powder dose into respirable particles the inhalers as described in these two applications are provided with deaggregation means provided within the air flow path.

The cavity and thereby the powder dose is protected before inhalation by two tapes, one covering the upper opening of the cavity and the other covering the hole in the lower part of the cavity thereby providing a moisture proof device.

However, the construction of the known devices is provided with several disadvantages.

The inhalers according to the above mentioned applications are constructed with a housing having an upper and a lower part sealed to each other wherein the two parts are made of different materials. The upper part is made of plastic material whereas the lower part in which the powder compartment or cavity is placed is made of aluminium or a laminate of aluminium and plastics. Furthermore, the cavity and thereby the hole in the cavity are provided in an unprotected manner and the cavity can easily be damaged during handling and storage of the inhalers. Moreover, as the hole is provided in the lower part of the cavity it is easily covered by a users thumb or hand during inhalation whereby the function of the

inhaler is jeopardised as the dose or parts of the dose may not be properly lifted out of the cavity.

These disadvantages are solved by the inhalation device according to the present invention.

The present invention provides a disposable breath-actuated dry-powder inhalation device of the above mentioned kind wherein the disadvantages of the known devices are eliminated.

The present invention also provides a construction which is more stable and rigid than the prior devices. It is also cheap and easy to produce and uses as little aluminium or laminates of aluminium as possible in order to minimise the stress to the environment.

The inhalation device according to the invention could be manufactured in a transparent material in order to make it possible for the patient to inspect the inhalation device and the dose before and after inhalation.

The above objects of the present invention are achieved by the features set out in claim 1, whereby the powder compartment is formed as a cavity or indent in a plate and placed in the housing in the air flow path.

In the present inhalation device the hole in the powder compartment/cavity is protected and can not be damaged during handling and storage and/or be covered during inhalation.

Further advantages and objects are clear from the features as set forth in the appended claims 2 to 16.

The inhaler according to the invention is preferably manufactured by using a method as described in claims 17 to 19.

Brief description of the drawings

The device according to the present invention will now be described by way of example with reference to the appended drawings, wherein

Figure 1 shows an exploded view of a first embodiment of the present invention;

Figure 2 shows a schematic side view of the first embodiment as shown in figure 1;

Figure 3 shows a cross-sectional view of the first embodiment as shown in figure 1;

Figure 4 shows a preferred embodiment of the deaggregation means placed in the air flow path of an inhaler according to the present invention;

Figure 4a shows the first deaggregation means; and

Figure 4b shows the second deaggregation means as shown in figure 4.

Figure 5 shows schematically a metohd of producing the inhalation device as described in figures 1 to 4.

Detailed description of the drawings

A preferred embodiment of the invention will now be described with reference to figures 1, 2 and 3.

As can be seen in figure 2 the inhalation device according to the invention comprises a substantially tubular housing 1 being substantially symmetrical around its longitudinal centre axis. Said housing consist of two parts, an upper part 2 and a lower part 3 being sealed together at their respective edges thereby forming an air flow path 4 for the inhalation air

flow. Said air flow path 4 is opened at both ends whereby one end forms an air inlet 5 and the second end forms an air outlet 6.

The sealing of the upper part 2 and lower part 3 may be effected in any known manner such as ultra sonic welding or heat sealing but also by gluing or by use of any other suitable sealing method. Said upper part 2 and lower part 3 are preferably formed of the same material such as polyethylene, polypropylene, polyester, polystyrene or similar and are preferably formed by heat-forming but any other methods may be used such as moulding. It is preferred that at least the upper part or top of the inhalation device is transparent in order to make it possible for the user to inspect the inhaler and the air flow path after inhalation to see whether the dose has been properly released and inhaled. The dose can also be inspected before inhalation.

A dose 7 to be inhaled is placed in a cavity 8. Said cavity is provided in a substantially flat plate 9. Said plate 9 is formed as an insert which is placed during manufacture of the device between the upper part 2 and lower part 3 of the housing 1 in the air flow path 4 close to the air inlet 5 of the inhaler. The cavity is substantially formed as a sphere segment and is preferably provided with one hole in or a group of holes 10 arranged around the centre of the segment.

Said lower part 3 is provided with a support surface 11 for the plate 9. Said support surface 11 is provided as a frame having three sides on which the plate 9 is placed as can be seen in figures 1 and 3. The open end of the support surface 11 is directed towards the air inlet 5 of the device. The air inlet allows air to enter both above and under the plate 9 and the cavity 8 as can be seen in figure 3. The air entering over the cavity creates a pressure difference between the region above and the region below the cavity 8 thereby facilitating the release, e.g. lifting, of the dose out of the cavity. If the cavity is provided with a hole 10 or a group of holes, a small amount of air will enter into the hole/holes thereby further improving the release of the dose.

The plate 9 is preferably made of aluminium or a laminate of aluminium and plastic sheet, and the cavity is formed conveniently in the plate by a using cold-forming procedure before the plate is placed in the housing.

After the cavity 8 has been formed in the plate 9 the powdered substance to be inhaled is filled into the cavity. When filling the substance an exact amount of substance must be metered and filled into the cavity and compacted to the desired degree in order to provide an exact dose so that the inhaler can function correctly. This can be achieved by using the method described in the International patent application PCT/SE95/00109.

In order to seal the dose 7 in the cavity 8 the cavity is covered by a first removable 12 sealing tape. If the cavity 8 is provided with a hole 10 a second removable sealing tape 13 is provided to cover said hole or each hole if more than one is present. It is of utmost importance to provide a moisture proof sealing for the dose in the cavity as most finely divided powdered substances are not stable if subjected to moisture. The removable sealing tapes provide a sealing and a cover for the dose during handling and storage and the tape or the tapes can be easily removed before inhalation. The first and second tapes are placed in position directly after the filling of powdered substance into the cavity. The tape is preferably made of laminates of plastic materials and aluminium but any other suitable material can be used.

The upper surface of the upper part 2 in the preferred embodiment forms a mouth piece 15 with the end portion of the lower part 3 around air outlet 6. The said upper surface of the upper part 2 may be provided with a guidance of how far the inhaler shall be inserted into the mouth of the user. A guiding element 60 is formed by shaping the upper part 2 and this guiding element reduces the cross-section of the air flow path at a distance from the air outlet and the position of the dose. Tests have shown that such reduction of the cross-section of the air flow path can be positioned at a distance of about 2 to 4 cm along the length seen from the air outlet 5 without giving rise to any negative effect on the flow characteristics of the device.

In order to break down substance in the form of aggregates into primary particles during inhalation deaggregation means are provided in the air flow path.

In the first preferred embodiment several sets of oblique planar surfaces are provided along the path of the air flow. Said surfaces provide constrictions in the air flow path which will increase the speed of inhalation air flow during its passage out along the air flow path. The surfaces or walls of the deaggregation means are disposed generally perpendicular to a plane through the longitudinal axis of the tubular housing and cover the whole cross-section of the housing. Aggregates and/or particles will thereby be forced to impact on the walls of the housing and the surfaces provided in the air flow path.

Tests have shown that the breakdown of aggregates into the primary particles is related to the positions and angles of said surfaces as well as the dimensions of the cross sections of the air flow path at different positions. A preferred embodiment of the deaggregation means will be described with reference to figs. 4, 4a and 4b.

In the preferred embodiments the deaggregation means have substantially two different forms and constructions.

The first deaggregation means 20a, 20b and 30a, 30b are formed as bodies having pairs of surfaces or walls 21a, 21b and 31a, 31b respectively, extending with an angle α_a and α_b, respectively, to the main direction of the air flow and the longitudinal centre axis of symmetry of the air flow path and the device seen from the air inlet to the air outlet. Said longitudinal centre axis is marked with X-X in figures 4, 4a and 4b. Said pairs of walls extend from the edges of the housing on both sides of the air flow path symmetrically and are spaced apart so as to provide a passage for the air flow and a restriction in the air flow path. The first pair of walls 21a, 21b are placed adjacent the release area of the dose 7. Said pairs of walls 21a, 21b and 31a, 31b are connected to a part 22a, 22b and 32a, 32b respectively being longitudinal in the direction of the air flow. Said longitudinal parts extend parallel to the main direction of the air flow and are spaced apart so as to provide a passage

for the air flow. The other end of said longitudinal parts 22a, 22b and 32a, 32b are connected to walls 23a, 23b and 33a, 33b respectively which together with the first wall and the longitudinal part of each deaggregation means substantially form a quadrangle 20a, 20b, 30a, 30b respectively, see figure 4. In figure 4a this preferred embodiment of is shown schematically.

The second deaggregation means 40, 50 are also formed as bodies having pairs of surfaces or walls preferably provided as quadrangles being symmetrical around their longitudinal axis as can be seen in figures 4 and 4b. They are provided in the centre of the air flow path 4 and the longitudinal axis of symmetry y-y of the quadrangles 40, 50 coincide with the longitudinal axis of symmetry X-X of the housing 1 and thereby the air flow path 4. Said quadrangles 40 and 50 are formed with a pair of surfaces or walls 41a, 41b and 51a, 51b respectively. The walls 41a, 41b and 51a, 51b in each quadrangle 40 and 50 are connected to each other at an angle which is directed to the centre axis of the main direction of the air flow seen from the air inlet to the air outlet and placed on the axis of symmetry of the housing. Two walls 41a, 41b and 51a, 51b are thereby placed with angles β and δ, respectively, to the main direction of the air flow and the longitudinal axis of symmetry of the air flow path and the device seen from the air inlet to the air outlet. The preferred embodiment of the second deaggregation means 40 and 50 are shown in figures 4 and 4b.

The first and second deaggregation means 20a, 20b, 30a, 30b and 40, 50 are positioned in the air flow path in a manner which give rise to acceleration areas for the air flow and the aggregates/particles as well as guidance whereby the aggregates and/or particles are forced to impact on the walls of said deaggregation means.

The form of the deaggregation means has been determined by tests and the most optimal forms for the above mentioned purpose have shown to be the ones represented in figure 4. The forms of the deaggregation means are also of importance for non-retention of substance in the air flow path as well as for the air flow resistance of the inhaler.

The tests have shown that the values of the angles α_a, α_b and β, δ are of utmost importance for the function of the deaggregation means and thereby the function of the inhaler. Several tests have been carried out with different substances and the values of the angles have been determined out of an optimisation of the different parameters which influences the performance of the air flow during inhalation. It has thereby been important to minimise the retention and the flow resistance as well as maximise the deaggregation at a typical air flow rate which depends on the inhalation force of a patient using the inhalation device.

The tests have shown that the α_a and α_b should be substantially about 30° to the main direction of the air flow seen from the air inlet to the air outlet and to a longitudinal axis being parallel to the longitudinal axis of symmetry of the device.

The value of the angle β is substantially about 45° to the main direction of the air flow seen from the air inlet to the air outlet and to the longitudinal axis of the device.

The value of the angle δ is substantially about 60° to the main direction of the air flow seen from the air inlet to the air outlet and to the longitudinal axis of the device.

When the inhaler is to be used, the inhaler is held more or less horizontal with the lower part 3, i.e. the part on which the plate 9 with the cavity 8 containing the dose 7 is placed, facing downwards. The free end of the sealing tape 12, and if a hole 10 is provided in the cavity 8, sealing tape 13 is pulled outwardly and the powder in the powder compartment 8 is exposed. The user then inserts the air outlet 6 which in one preferred embodiment is formed as a mouth piece 15 into the mouth until the upper lip is in contact with the guiding element 60 and inhales through the inhaler. The resultant air flow through the inhaler will become very turbulent in the region of the cavity and the dose of pharmaceutical powder will be lifted out of the powder compartment and mixed with the air-flow. Any aggregates created in the powder dose will impact on the planar surfaces of the deaggregation means and break down into primary particles.

The inhaler according to the invention is preferably manufactured and filled by using a method as described in the above mentioned International patent application PCT/SE95/00109. Said method can easily be modified to be used to manufacture a disposable inhaler according to the present invention.

The plate 9 is formed from an elongate layer of a first material 109 provided from a first roller 61. The cavities 8 are formed as spherical segments at predetermined spaces from each other along the length of the elongate layer in a forming station 62. In the embodiment in which a hole 10 or a group of holes is provided in the cavity this hole or these holes are punched out in or around the centre of the sphere segment forming the cavity either when the cavity is formed or in a punching station 63. In the following filling station 64 a pharmaceutically active substance is filled into the cavities one by one and compacted by using the method described in the above mentioned International patent application. After the filling of a cavity, the cavity and the dose are covered by at least a first sealing tape 12. Said first sealing tape 12 is provided as a cover on the upper side of the cavity. In the embodiment with a hole or a group of holes provided in the cavity a second sealing tape 13 is provided at the bottom or back side of the cavity thereby covering the hole or group of holes in the cavity. Both of these tapes are provided in the same step in the tape station 65.

The housing 1 of the inhaler is formed in separate production lines by providing a second elongate layer 102 and a third elongate layer 103 of material from a second roller 71 and a third roller 81. Said second elongate layer 102 and third elongate layer 103 are formed to the upper part 2 and lower part 3 of the housing respectively in forming stations 72 and 82. Thereby preferably the upper part 2 is formed with the mouth piece 15 and the guiding element 16 as described above. The lower part 3 is formed with the support surface 11 for the plate 9 and the deaggregation means 20a, 20b; 30a, 30b; 40; 50 as described above.

After the forming of the upper part 2 and lower part 3, they are cut into predetermined pieces i cutting stations 73 and 83 respectively.

The lower part 3, in which the support surface 11 and the deaggregation means 20a, 20b; 30a, 30b; 40; 50 have been formed, is moved to a station 91 where the elongate layer 109, in which plates 9 with cavities 8 have been formed, filled and sealed in a parallel production line, are continously placed on the support surfaces 11 of the lower part 3. The plates 9 are fixed to the corresponding lower part 3 of the housing by using any known suitable method such as gluing, isostatic pressing, heat sealing or welding, e.g. laser-, ultra sonic-, heat- or cold-welding in a fixing station 92. The lower parts 3 moved to a station 93 where the upper parts 2 is placed on top of said lower parts 3 with the plates 9, whereby an upper part 2 of the inhaler is placed on a corresponding pre-formed lower part 3 in such a manner that the housing of the inhalation device is formed.

Said upper part 2 and lower part 3 are thereafter sealed together in a sealing station 94. Also here any known sealing/fixing method can be used such as gluing, heat sealing or welding methods such as e.g. laser-, ultra sonic-, heat- or cold-welding. Thereafter the devices, still being in the form of a continuos layer, is moved to a further cutting station 95 where the excess material from the plates are cut away and the inhalation devices are separated from each other. The disposable inhalers according to the present invention are hereby formed.

The inhalation device of the present invention is intended to be used with any substances suitable for administration, i.e. any substances which may be administered by inhalation. Suitable inhalable medicaments may include for example β2-adrenoreceptor agonists for example salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators for example ipratropium bromide and the like; glucocorticosteroids for example beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and the like, and their pharmacologically acceptable esters and salts; anti-allergic medicaments for example sodium cromoglycate and nedocromil sodium;

expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic- antiparasitic- and anticancer- medicaments, sedatives and analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal and antihypotension medicaments, vaccines, antiviral medicaments, proteins, polypeptides and peptides for example peptide hormones and growth factors, polypeptides vaccines, enzymes, endorphines, lipoproteins and polypeptides involved in the blood coagulation cascade, vitamins and others, for example cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

Modifications

The disposable inhaler according to the invention as described above can of course be modified within the scope of the appended claims.

Thus the upper part 2 of the housing can be formed without a guidance for the user of how far the inhaler shall be inserted into the mouth.

Furthermore, in the preferred embodiment the first and second deagglomeration means are formed as quadrangles having the described form. It is however clear that the form of the deagglomeration means can be varied. The important characteristics of the deagglomeration means are the angles of the walls in relation to the main direction of the air flow. The "backside" of the deagglomeration means could have any form which do not give rise to an increased retention of substance and a restriction of the speed of the air flow.

The values of angles α_a, α_b and β, δ may be changed although the performed tests show that the most optimum values of these angles are the ones as claimed in the appended claims and stated above.

In the preferred embodiment the mouth piece is formed in the upper part of the housing and the support surface for the plate and the deaggregation means are formed in the lower part of the housing. This could of course be changed and the mouth piece, the guiding element, the support surface and the deaggregation means could be formed in any of the parts of the housing. The deaggregation means could also be formed as inserts being pre-formed and inserted into the air flow path of the housing.

Claims

1. Disposable inhaler comprising a tubular housing (1) forming an air flow path (4) being open at both ends, one end forming an air inlet (5) and one end forming an air outlet (6), said housing comprising a compartment (8) for storing a pharmaceutically active substance to be inhaled, said compartment (8) being placed in the air flow path close to the air inlet, c h a r a c t e r i s e d in that the powder compartment (8) is formed as a cavity or indent in a plate (9) and placed in the housing (1) in the air flow path (4).

2. Disposable inhaler according to claim 1, c h a r a c t e r i s e d in that said powder compartment (8) is provided with at least one hole (10) into which air enters and lifts powder out from the compartment (8) and mixes it with the air stream during inhalation.

3. Disposable inhaler according to claim 1 or 2, c h a r a c t e r i s e d in that said housing (1) comprises an upper part (2) and a lower part (3) being sealed together along longitudinal edges.

4. Disposable inhaler according to any of claims 1 to 3, c h a r a c t e r i s e d in that deaggregation means (20a, 20b, 30a, 30b, 40, 50) are provided in the air flow path (4) between the powder compartment (8) and the air outlet (6).

5. Disposable inhaler according to claim 4, c h a r a c t e r i s e d in that said deaggregation means (20a, 20b; 30a, 30b; 40; 50) form an air flow path with constrictions and extensions providing guidance and acceleration to the air flow and the dose mixed in the air flow during inhalation.

6. Disposable inhaler according to claim 5,
c h a r a c t e r i s e d in that said deaggregation means (20a, 20b; 30a, 30b; 40; 50) comprise a plurality of substantially planar surfaces or walls (21a, 21b; 31a, 31b; 41a, 41b; 51a, 51b) being disposed substantially perpendicular to a plane through the longitudinal axis of the tubular housing, a projection of said surfaces onto a cross-section of the housing substantially covering said cross-section.

7. Disposable inhaler according to claim 6,
c h a r a c t e r i s e d in that first deaggregation means (20a, 20b, 30a, 30b) are provided as pairs of planar surfaces or walls (21a, 21b; 31a, 31b) extending from the edges of the housing on both sides of the air flow path and oriented at an angle α_a, α_b respectively, relative to the longitudinal direction of the housing (1) from the air inlet (5) to the air outlet (6).

8. Disposable inhaler according to claim 7,
c h a r a c t e r i s e d in that the angle α_a, α_b is preferably substantially about 30°.

9. Disposable inhaler according to claims 6,
c h a r a c t e r i s e d in that second deaggregation means (40, 50) are provided as pairs of planar surfaces or walls (41a, 41b; 51a, 51b) positioned symmetrically around the longitudinal centre axis of the housing (1) and oriented at angles β and δ respectively, relative to the longitudinal direction of the housing (1) from the air inlet (5) to the air outlet (6).

10. Disposable inhaler according to claim 9,
c h a r a c t e r i s e d in that the angle β is preferably substantially about 45°
and in that the angle δ is preferably substantially about 60°.

11. Disposable inhaler according to any of the preceding claims, c h a r a c t e r i s e d in that the upper part (2) of the housing (1) with the end portion of the lower part 3 around air outlet (6) is formed as a mouth piece (15) intended to be placed in the mouth of the user when the dose is to be inhaled.

12. Disposable inhaler according to claim 11, c h a r a c t e r i s e d in that a guiding element (60) is provided in said upper part (2) at said mouth piece (15) , whereby said guiding part (60) provides a guidance for the user how to place the mouth piece (15) and the inhaler in the mouth for inhalation.

13. Disposable inhaler according to any of the preceding claims, c h a r a c t e r i s e d in that a first removable sealing tape (12) is provided on the plate (9) covering the cavity (8) and the dose therein.

14. Disposable inhaler according to claim 13, c h a r a c t e r i s e d in that a second removable sealing tape (13) is provided on the plate (9) covering the at least one hole (10) provided in the cavity (8).

15. Disposable inhaler according to any of the preceding claims, c h a r a c t e r i s e d in that the disposable inhaler is a dry-powder inhaler with pharmaceutically active substance present in the cavity (8).

16. Disposable inhaler according to claim 15, c h a r a c t e r i s e d in that the inhaler is a disposable, breath-actuated, dry-powder inhaler.

17. Method of manufacture a disposable inhaler according to claims 1 to 16, whereby

said cavities (8) are formed in said plates 9 provided from a first elongate layer (109) of a material being fed from a first roller (61) whereby said cavities being formed at a predetermined space from each other;

said cavities (8) are filled with a pharmaceutically active substance in a filling station (64);

said lower part (3) is formed from a third elongate layer (103) provided from a third roller (81) and cut into predetermined pieces;

each plate (9), formed in said first elongate layer (109), is placed at predetermined positions on a corresponding lower part (3) and fixed thereto;

said upper part (2) is formed from a second elongate layer (102) provided from a second roller (71) and cut into predetermined pieces;

one upper part (2) is placed on top of said lower part (3) with the plate (9) whereby the upper part (2) and the lower part (3) are fixed and sealed together thereby forming the inhalation device;

the inhalation devices are separated from each other by cutting the elongate layer (109) providing the plates (9) in a cutting station (95).

18. Method according to claim 17, whereby at least one hole (10) is provided in the cavity (8) before it is filled.

19. Method according to claim 17 or 18, whereby a first removable sealing tape (12) is placed over the cavity (8) covering the substance and sealing the cavity and whereby a second removable sealing tape (13) is placed to cover the hole of the cavity (8) before said plate (9) is placed in its position on the lower part (3) of the inhaler.

20. Use of a disposable inhaler as described in any of claims 1 to 16 for the inhalation of any inhalable pharmaceutically active substance.

21. Use according to claim 20, wherein the inhalable substance is a mixture comprising peptides or polypeptides.

Fig.1

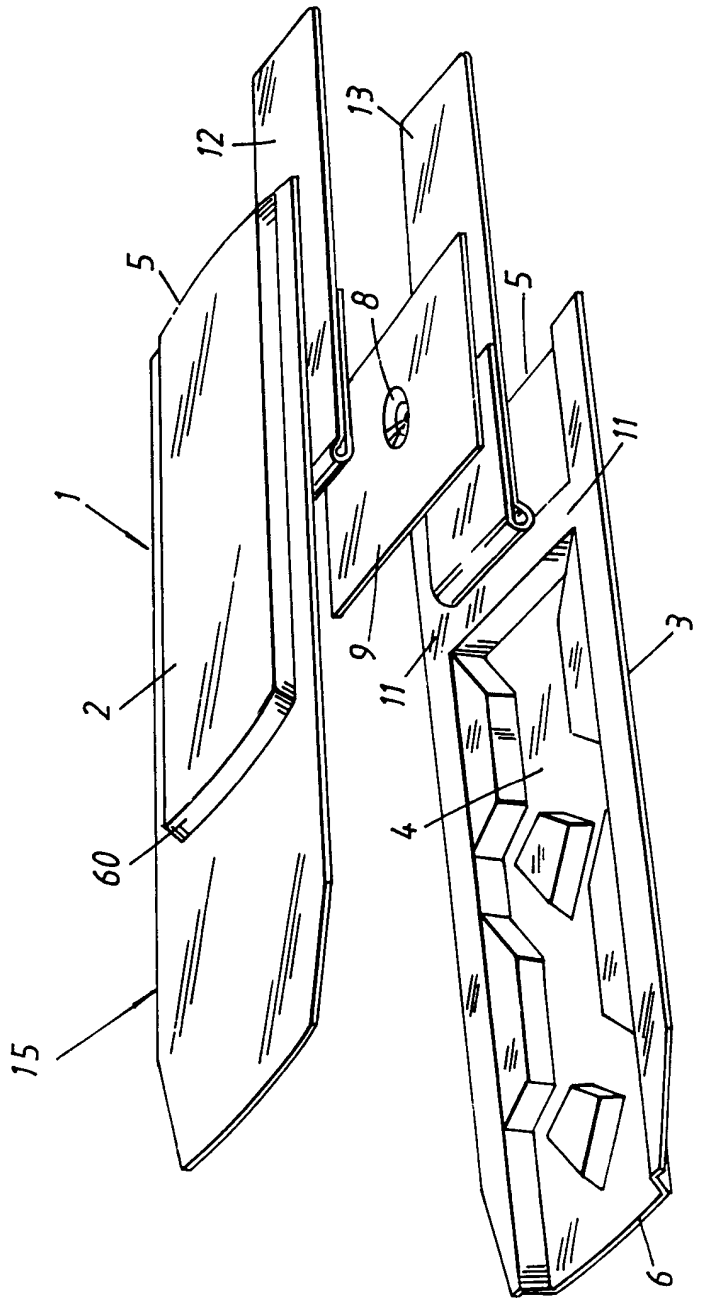


Fig. 2

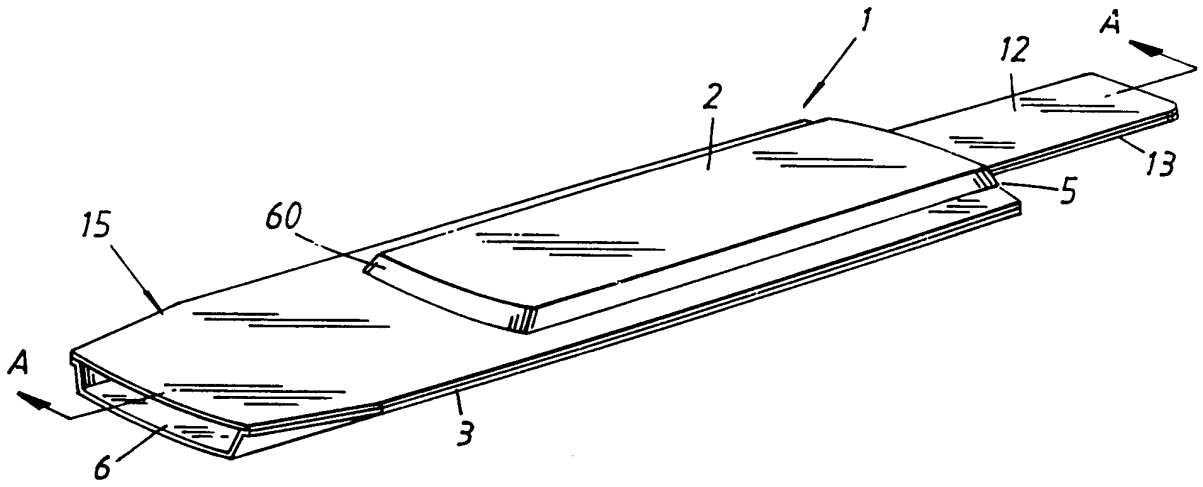


Fig. 3

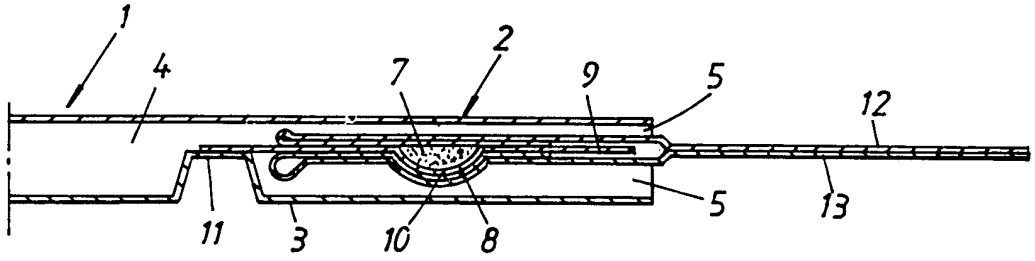


Fig. 4

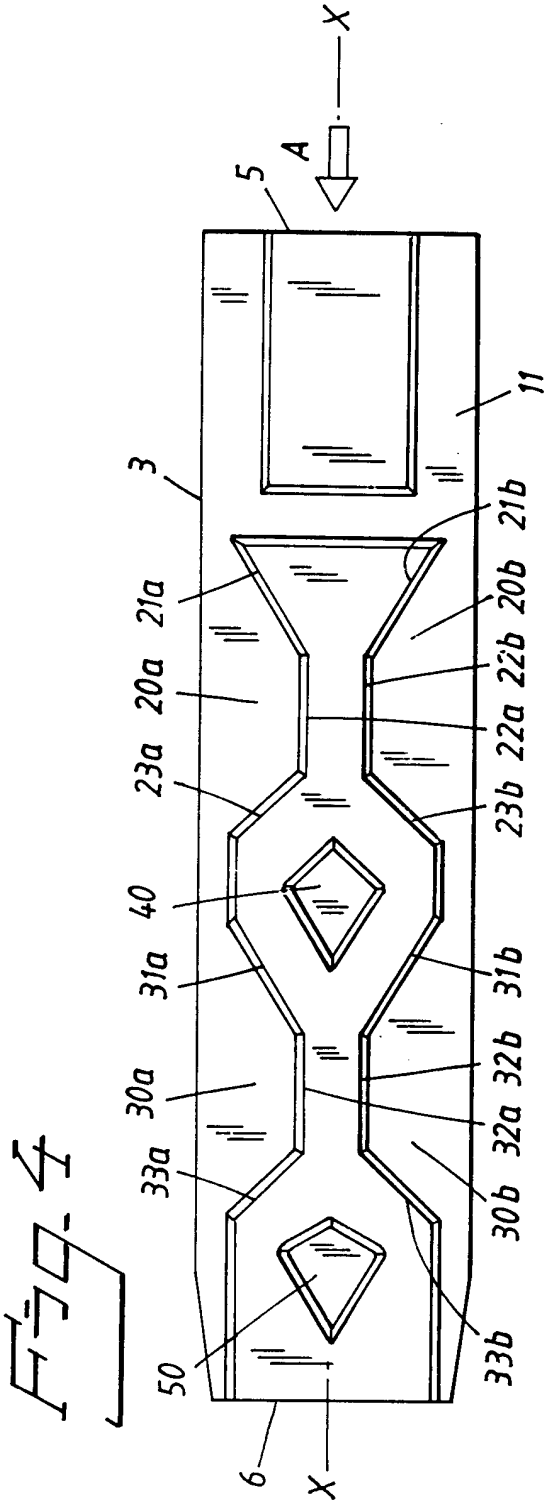


Fig. 4a

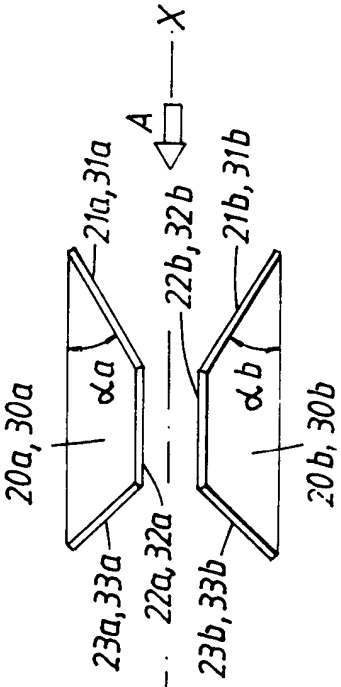
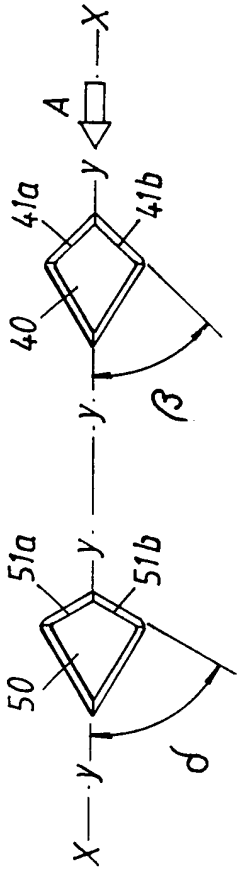


Fig. 4b



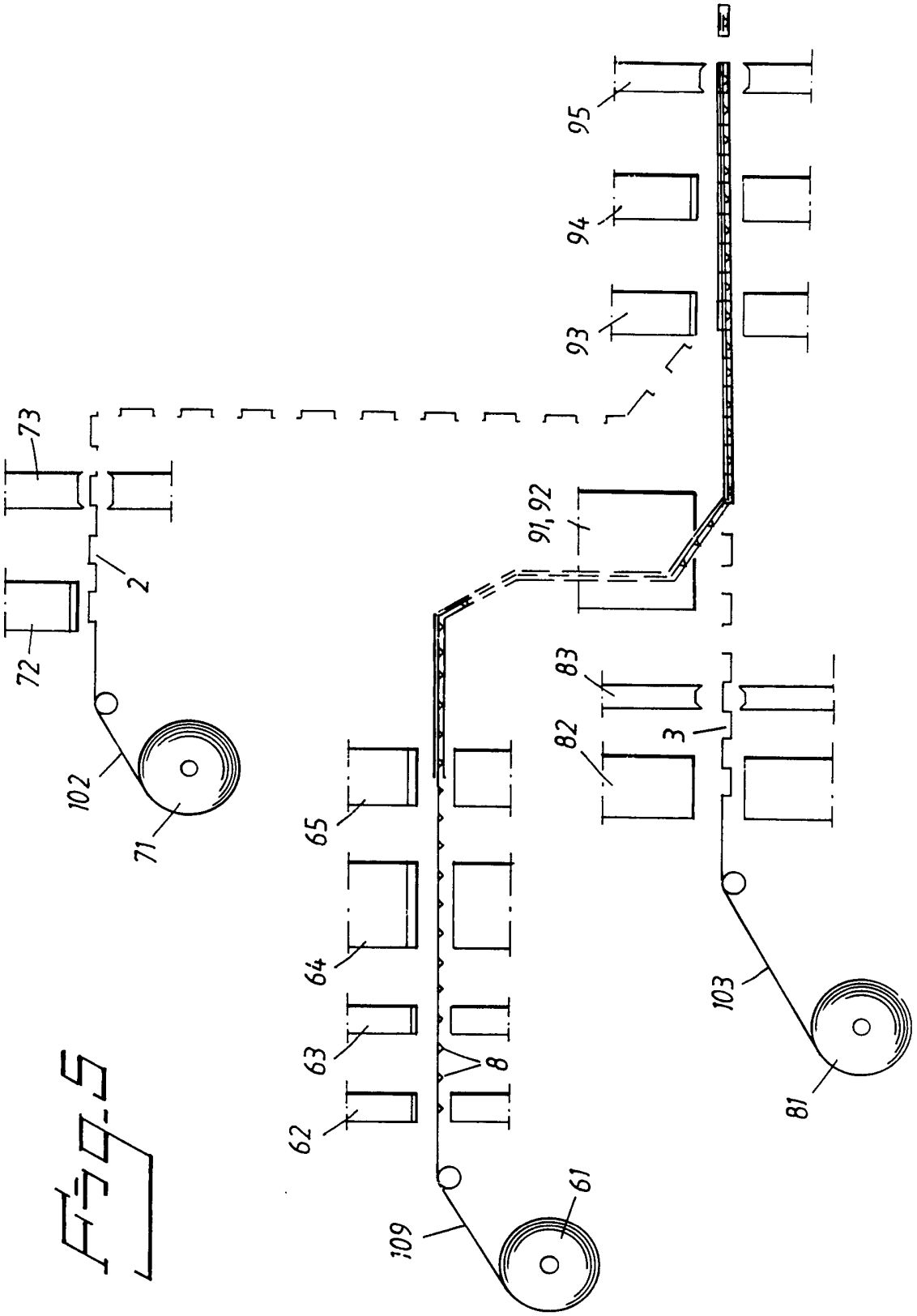


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 96/00970

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 15/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9317728 A1 (AKTIEBOLAGET ASTRA), 16 Sept 1993 (16.09.93) --	1-21
A	WO 9204069 A1 (AKTIEBOLAGET ASTRA), 19 March 1992 (19.03.92) --	1-21
A	US 5042472 A (LEONID BUNIN), 27 August 1991 (27.08.91) -- --------	1,2,13-16, 20-21

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 November 1996	25 -11- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Eva Johansson Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/10/96

International application No.
PCT/SE 96/00970

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